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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,610	12/15/2000	Chyi-Cheng Chen	20529/111697	2197

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BRYAN CAVE LLP  
1290 AVENUE OF THE AMERICAS  
33RD FLOOR  
NEW YORK, NY 10104

EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/26/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/738,610

**Applicant(s)**

CHEN ET AL.

**Examiner**

Brian S Kwon

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10,11 and 14-34 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-8 and 10-11 is/are allowed.
- 6) ☒ Claim(s) 22-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Summary of Action***

- I. The rejection of claims 1, 3-8 and 10-11 under 35 USC 103(a) is withdrawn in light of the amendment.
- II. Claims 22-24 and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al. (US 4605666).
- III. Claim 25 is rejected under 35 USC 103(a) as being unpatentable over Schmidt et al. (US 4605666) in view of Hill (US 3946110).

### ***Status of Application***

1. By Amendment filed May 9, 2003, Claims 2, 9, 12 and 13 have been cancelled and Claims 1, 8, 10 and 11 have been amended. 1, 3-8, 10-11 and 22-34 are currently pending for prosecution on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 22-24 and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al. (US 4605666).

Claims read on a powder or granule or compressed tablet composition comprising L-ascorbic acid and/or a pharmaceutical acceptable salt thereof, and about 0.1 to about 10% by

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weight of pectin, calculated based on the total weight of the composition thereof, wherein the composition having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutical acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder. Further limitations include “about 0.1 to 10% by weight” of an adjuvant and/or an excipient (i.e., dextrinized sucrose (Di Pac Sugar), microcrystalline cellulose and starch) in claim 23, 33 and 34; “a sodium ascorbate as the L-ascorbic acid salt” in claim 24; “a citrus pectin as the pectin” in claim 25; “the pectin is present in the composition at about 0.5% to about 5% by weight” in claim 26, more specifically “about 0.5% to about 2% by weight” in claim 27; “the composition consists of 95-99% by weight of L-ascorbic acid and/or a 5-1% by weight of pectin” in claim 28; and “about 0.5 to 4% by weight” of the lubricant or a mixture of lubricants (i.e., stearic acid, a magnesium salt of stearic acid, a calcium salt of stearic acid and glyceryl behenate 45 (Compritol 888 ATO)) in claims 30-32.

Schmidt expressly teaches a powder or tablet composition, comprising a water-soluble vitamin (i.e., sodium ascorbate, ascorbic acid); a binder (i.e., microcrystalline cellulose); a lubricant (i.e., stearic acid, magnesium stearate, calcium stearate) and an excipient (i.e., pectin, starch), wherein the final powder formed will contain at least 80% (preferably at least 90) percent by weight of the water soluble vitamin, less than 15 (preferably less than 9) percent by weight of binder...0.2 to 5 percent by weight of the lubricant and less than 3 percent of other excipients. (column 1, line 36 thru column 2, line 53; column 2, line 54 thru column 3, line 2).

One of ordinary skill in the art is able to “at once envisage” the claimed composition within the sufficiently limited or well-delineated components and their dosage ranges, the composition is anticipated.

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Although Schmidt is silent about the functional characteristic of using pectin as a binder, such property or characteristic must be inherent to the pectin. Therefore, the claimed composition is still properly rejected by a reference, even if the reference does not address or acknowledge the property.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (US 4605666) in view of Hill (US 3946110).

The teaching of Schmidt has been discussed in above 35 USC 102(b) rejection.

Hill discloses the use of pectin, namely citrus pectin, in preparing medicinal tablet composition (Examples 9-16). Hill also discloses that pectins are commonly found in edible fruits and vegetables, including apples and citrus fruits, and are generally isolated from them.

The teaching of Schmidt differs from the claimed invention in the use of citrus pectin in said composition. To incorporate such teaching into the teaching of Schmidt, would have been obvious in view of Hill who teaches the use of citrus pectin in preparing pharmaceutical tablet composition.

One having ordinary skill in the art would have expected in view of Hill that citrus pectin would be preferred in preparing pharmaceutical tablet composition, maybe due to its lighter color than other source of pectins. Furthermore, one having ordinary skill in the art would have been motivated to modify the teaching of Schmidt, with the reasonable expectation of success, such that said composition can be readily formed into tablet when it is compressed.

### Conclusion

4. Claims 1, 3-8 and 10-11 are allowed.
5. Claims 22-34 are rejected.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1600**

A handwritten signature in black ink, appearing to read 'Zohreh Fay', written in a cursive style.